

REMARKS

The Office Action mailed August 25, 2008, has been received and carefully noted. The above amendments and the following remarks are being submitted as a full and complete response thereto.

Prior to entry of this amendment, Claims 1-12 were pending in the application, and Claims 6-8 were withdrawn from consideration. Claims 1-5 and 9-12 are amended in order to meet formal requirements. New Claim 13 is introduced. Thus, Claims 1-5 and 9-13 are pending in this application. In particular, it is to be noted the amended claims and new added claim do not introduce new matter, since they contain only limitations that were already disclosed in the original specification and claims.

Claim Rejections - 35 U.S.C. §112

In the present Office Action, the Examiner states that Claims 1-5 and 9-12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In order to overcome the Examiner's rejection, the insufficient antecedent basis pointed out by the Examiner about Claim 1 has been corrected.

Please note that the limitation "the quantities" in line 8 has not been amended since in Applicant's opinion there is sufficient antecedent basis for this limitation in the expression "each capsule having ... a body containing a quantity of pharmaceutical material" in line 3 of Claim 1. Consequently, Applicant respectfully requests the withdrawal of these rejections.

Claim Rejections - 35 U.S.C. §103

In the present Office Action, the Examiner states that Claims 1-5 and 9-12 are rejected under 35 U.S.C. §103(a) as being unpatentable over admitted prior art (Background of the invention) in view of Trebbi (U.S. Patent No. 6,327,835, hereinafter "Trebbi"). Applicant respectfully disagrees with the Examiner.

Indeed, the Background of the invention discloses a capsule filling machine in which the only quality control on the capsules is performed in a statistic way by high precision scales at the end of the production process.

As stated by the Examiner, Trebbi discloses a capsule filling machine having detecting means to check out the quantity of the material filled into the capsules body. Nevertheless, Trebbi also discloses that the machine comprises **volumetric metering devices** (numbered as 8 and 9) comprising a hollow punch (18) inside which there is movably arranged a small piston (19). The metering devices (8) on one side is immersed in a product store (13) so as **to isolate respective volumetrically predefined metered amounts (D) of the said product.**

The distance of the piston (19) from the lower edge of the hollow punch (18) defines the volume of this hollow punch available for filling with the product, and determines the consequent volume and the weight of the metered amount of the said product to be formed.

Moreover, the piston (19) and the hollow punch (18) are mounted on a pressing thruster (6). The pressing thruster (6) is provided with **force transducers** which are able to emit an electrical signal having a value proportional to the thrust which these

thrusters exert on the metered amount of product isolated in the hollow punch of the metering devices, so that, for the same stroke of the thrusters, **with the transducers in question it is possible to detect a parameter relating to the resistance which the thrusters encounter during pressing and therefore proportional to the density of the product processed** and to the volume of the metered amount of product pressed and therefore to mass or the weight of the metered amount itself.

In other words, the machine described in Trebbi can estimate the quantity (the mass) of the pharmaceutical material filled into each capsule body by means of an indirect measurement of the density and of a known value of the volume.

In Applicant's opinion, it is clear that Trebbi does not disclose means for detecting and **volumetrically checking** the quantity of pharmaceutical material filled into each capsule body as specifically claimed under 35 U.S.C. 112, sixth paragraph. Moreover, Trebbi does not disclose transducer means **for measuring the volume** of said quantities of material as specifically claimed under 35 U.S.C. 112, sixth paragraph.

In view of the above, the combination of Trebbi with the admitted prior art does not lead to the claimed solution. Certain clearly claimed limitations are not taught or suggested. Absent a teaching of the specifically claimed function, there can be no teaching of the means plus function limitation. Therefore, clear differences exist between the prior art relied upon and present Claim 1, such that Claim 1 would not have been obvious over admitted prior art (Background of the invention) in view of Trebbi. Claims 2-5 and 9-12 are patentable as well since they depend on non-obvious Claim 1. Applicant respectfully requests that the claim rejections under 35 U.S.C. §103 be withdrawn.

As for new Claim 13, Applicant believes that this claim is not obvious in view of the available prior art. Trebbi does not disclose any transducer element for measuring a volume of said quantities before they are inserted into the capsule bodies. Moreover, Trebbi does not disclose that the transducer element comprises a sliding detector element entering in a respective dosing chamber associated with the carousel of the filling machine to measure a height reached by the quantity of pharmaceutical material in the dosing chamber.

Indeed, as already stated above, Trebbi discloses volumetric metering devices (numbered as 8 and 9) comprising the hollow punch (18) inside which there is a movable arranged a small piston (19) to isolate volumetrically predefined metered amounts of the product. The volume of the predefined metered amounts of the product is defined by the **fixed distance** of the piston (19) from the lower edge of the hollow punch (18).

In the Trebbi's machine, the force transducer measures indirectly the density of the material by measuring the force necessary to penetrate in the material for the same stroke of the thrusters. Consequently, in Applicant's opinion even claim 13 is patentable, since it is not obvious over the available prior art.

In view of the foregoing, reconsideration and withdrawal of the above rejections is respectfully requested.

Conclusion

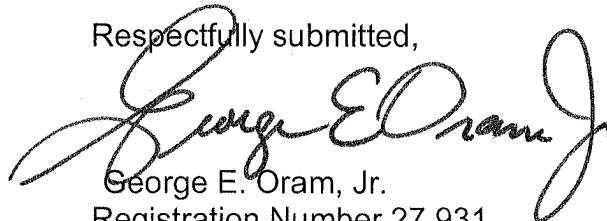
All matters having been addressed above and in view of the pending claims and remarks, Applicant respectfully requests the entry of this Amendment, the Examiner's reconsideration of the application, and the timely allowance of the pending claims.

Applicants' counsel remains ready to assist the Examiner in any way to facilitate and expedite the prosecution of this application.

Applicant respectfully submits that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event that this paper is not being timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account Number 01-2300, referencing Docket Number 023349-00315.

Respectfully submitted,



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